Docket No. COD0183USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Sigmund Kulessa	Confirmation No.:	6484
Appln. No.	:	10/676,326	Art Unit :	3763
Filed	:	September 20, 2003	Examiner :	Bouchelle, Laura A.
Title	:	TWO-COMPARTMENT REDUCED VOLUME INFUSION PUMP		

CERTIFICATE OF TRANSMISSION			
I hereby certify that this correspondence is being electronically filed via EFS-Web to the Commissioner for Patents with the U.S. Patent and Trademark Office on: April 27, 2010			
Name (print/type)	Eugene L. Szczecina, Jr.		
Signature	/Eugene L. Szczecina, Jr./	Date	April 27, 2010

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was mailed by Appellant to the U.S. Patent & Trademark Office on January 27, 2010, which was filed in response to the Final Office Action of October 27, 2010.

Real Party In Interest:

By virtue of an assignment recorded at reel/frame 014570 / 0296 this application is assigned to Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, MA 02767, a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 2, 14, 25, 37, 43 and 51 have been cancelled.

Claims 1, 3-13, 15-24, 26-36, 38-42, 44-50 and 52-57 are pending, have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of October 27, 2009.

Summary of Claimed Subject Matter:

The present invention, as exemplified by independent claim 1, is directed to an infusion apparatus that is implantable in a human body. The infusion apparatus comprises a medication reservoir 102 for storing a medication 104; (see page 5, lines 10-11; Figures 2 and 3). A carrier reservoir 106, for storing a carrier 108, is larger than the medication reservoir 102; (see page 5, lines 11; Figure 2).

A mixing chamber 124 is included in which the medication and carrier are thoroughly mixed, thus diluting the medication with the carrier. The mixing chamber 124 is a micro fluidic chip 128 having a capillary pathway disposed in a serpentine pattern; (See page 7, line 5-10; Figures 4A and 4B).

A medication flow path 136 fluidly connects the medication reservoir 102 to the mixing chamber 124; (See page 7, lines 20-23; Figures 5 through 9). A carrier flow path 138 fluidly connects the carrier reservoir 106 to the mixing chamber 124; (See page 7, lines 21-22; Figures 5 through 9). A medication pump system 144 discharges the medication to the mixing chamber 124; (See page 9, lines 1-2; Figure 8). A carrier pump system 146 discharges the carrier to the mixing chamber 124; (See page 9, lines 2-3; Figure 8).

An outlet port 148 fluidly connects to the mixing chamber 124 for discharging a diluted medication/carrier mixture; (See page 10, line 4-5; Figures 1 and 10). A bolus port is disposed between the mixing chamber 124 and the outlet port 148. (See page 10, lines 8-9; Figure 10).

The present invention, as exemplified by independent claim 19, is directed to an infusion apparatus. The infusion apparatus comprises a medication reservoir 102 for storing a medication 104; (see page 5, lines 10-11; Figures 2 and 3). A carrier reservoir 106, for storing a carrier 108, is larger than the medication reservoir 102; (see page 5, lines 11; Figure 2).

A mixing chamber 124 is included in which the medication and carrier are thoroughly mixed, thus diluting the medication with the carrier. The mixing chamber 124 is a microfluidic chip 128 having a capillary pathway disposed in a serpentine pattern; (See page 7, line 5-10; Figures 4A and 4B)

A medication flow path 136 fluidly connects the medication reservoir 102 to the mixing chamber 124; (See page 7, lines 20-23; Figures 5 through 9). A carrier flow path 138 fluidly connects the carrier reservoir 106 to the mixing chamber 124; (See page 7, lines 21-22; Figures 5 through 9). A medication pump system 144 discharges the medication to the mixing chamber 124; (See page 9, lines 1-2; Figure 8). A carrier

pump system 146 discharges the carrier to the mixing chamber 124; (See page 9, lines 2-3; Figure 8).

An outlet port 148 fluidly connects to the mixing chamber 124 for discharging a diluted medication/carrier mixture; (See page 10, line 4-5; Figures 1 and 10). A bolus port is disposed between the mixing chamber 124 and the outlet port 148. (See page 10, lines 8-9; Figure 10).

The present invention, as exemplified by independent claim 42, is directed to a method of infusing medication comprising the following steps:

Storing a medication in a medication reservoir (step 200); (see page 12, line 5-6; Figure 12);

Storing a carrier in a carrier reservoir, wherein the carrier reservoir is larger than the medication reservoir (step 202); (See page 12, line 6-7; Figure 12);

Discharging the medication to a mixing chamber (step 204); (See page 12, line 8-9; Figure 12);

Discharging the carrier to the mixing chamber (stop 206); (See page 12, line 8-9; Figure 12);

Mixing the medication with the carrier in the mixing chamber to dilute medication and form a medication/carrier mixture (step 208); (See page 12, line 9-10; Figure 12). The mixing chamber 124 is a micro fluidic chip 128 that has a capillary pathway disposed in a serpentine pattern; (See page 7, line 5-10; Figures 4A and 4B);

Discharging the diluted medication/carrier mixture (step 210); and (See page 12, line 12); and

Introducing a bolus dosage into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture (step 212). (See page 12, line 11).

The present invention, as exemplified by independent claim 50, is directed to a method of infusing medication comprising the following steps:

Storing a medication in a medication reservoir (step 200); (see page 12, line 5-6; Figure 14);

Storing a carrier in a carrier reservoir, wherein the carrier reservoir is larger than the medication reservoir (step 202); (See page 12, line 6-7; Figure 14);

Controling the discharging of the medication to a mixing chamber (step 228); (See page 12, line 8-9 and page 13, lines 4-6; Figure 14);

Discharging the carrier to the mixing chamber (stop 206); (See page 12, line 8-9; Figure 12);

Mixing the medication with the carrier in the mixing chamber to dilute medication and form a medication/carrier mixture (step 208); (See page 12, line 9-10; Figure 14). The mixing chamber 124 is a micro fluidic chip 128 that has a capillary pathway disposed in a serpentine pattern; (See page 7, line 5-10; Figures 4A and 4B);

Discharging the diluted medication/carrier mixture (step 210); and (See page 12, line 12; Figure 14); and

Introducing a bolus dosage into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture (step 212). (See page 12, line 11).

Grounds of Rejection To Be Reviewed On Appeal:

A) Whether the final rejection stating that claims 1,3-13, 15-24, 26-36,38-42,44-50,52-56 are unpatentable under 35 U.S.C. 103(a) should be reversed.

Argument:

Rejection of claims 1,3-13, 15-24, 26-36,38-42,44-50,52-56 under 35 USC 103(a)

The Examiner has finally rejected claims 1, 3-13, 15-24, 26-36, 38-42, 44-50 and 52-56, under 35 U.S.C 103(a) as being unpatentable over US Patent No. 4,193,397 to Tucker et al (hereinafter referred to as "Tucker") in view of US Publication No. 2003/0133358 to Karp (hereinafter referred to as "Karp") in view of US Patent No. 6,620,151 to Blischak et al (hereinafter referred to as "Blischak").

The present invention is directed to an infusion apparatus and a method of infusing medication as represented by the pending claims. The apparatus includes a medication reservoir and a carrier reservoir. By separating these two reservoirs the overall size of the implantable apparatus can be reduced because relatively high concentrated medication can be contained in one reservoir while the carrier fluid, for example saline, is contained in the carrier reservoir. In addition, the number of times the patient would need a refill of the medication can be reduced. To achieve this goal, the medication and the carrier must mix in a mixing chamber sufficiently to allow for dilution of the medication and carrier fluids so that the patient will receive the proper dose. As illustrated in Figures 4A and 4B, in one embodiment the mixing chamber is a microfluidic chip 128. The chip includes a pathway 134 that includes convolutions to allow the medication sufficient contact time with the carrier to allow for thorough mixing. In addition, a bolus port 150 is disposed between mixing chamber 124 and outlet port 148. Bolus port 150 allows a doctor to introduce a bolus dose into apparatus 100, after medication 104 and carrier 108 have been mixed, but prior to the diluted mixture being discharged from apparatus 100.

As Applicant's pointed out in the originally filed specification, Tucker discloses a basal reservoir containing medication of a certain dosage and a smaller bolus reservoir containing high concentrate medication. The basal reservoir discharges medication to the patient at a specified rate. The basal reservoir discharges the high concentration of medication to a smaller accumulator and, at a specified time, the accumulator discharges the bolus dose into the basal medication discharge.

However, Tucker's bolus dose is never mixed and diluted with the basal dose. The bolus dose is sent as a short 'burst' of medication at timed or triggered intervals.

Independent claims 1, 19, 42 and 50 make it clear that a bolus port is disposed between the mixing chamber and the outlet port, or that a bolus dosage is introduced into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture. Since Tucker's infusion apparatus already includes a bolus reservoir, one of ordinary skill in the art would not have found it obvious to add a completely redundant bolus port between the mixing chamber and the outlet port, as claimed in the present invention.

In an attempt to render the present invention as being obvious to one of ordinary skill in the art, the Examiner appears to use somewhat circular and confusing logic to add an additional bolus reservoir to Tucker's apparatus. The Examiner's original rejection was bases upon a combination of Tucker and Karp alone. On page 4 of the Examiner's Final Rejection (dated October 27, 2009), the Examiner admits that "yes it does seems as though the [Tucker's] device already contains a bolus port." The Examiner argues that while Tucker calls his bolus reservoir, he really doesn't mean it. Appellant's respectfully disagree. Tucker's bolus port is intended to deliver a bolus dose, which is sent as a short 'burst' of medication at timed or triggered intervals. The generally accepted meaning of a bolus reservoir is a reservoir that delivers a short burst of medication just as Tucker's does. Thus, Appellant's maintain that one of ordinary skill in the art would not have found it obvious to add a completely redundant bolus port between the mixing chamber and the outlet port, as claimed in the present invention, regardless of the teachings of Blischak.

Conclusion:

For the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 1, 3-13, 15-24, 26-36, 38-42, 44-50 and 52-56, under 35 U.S.C 103(a) should be reversed.

Respectfully submitted,

By:__/Eugene L. Szczecina, Jr./___
Eugene L. Szczecina, Jr.
Reg. No. 35029

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1479
Dated: April 27, 2010

Claims Appendix

An appendix containing a copy of the claims involved in the appeal.

1. (Previously Presented) An infusion apparatus implantable in a human body, comprising:

a medication reservoir for storing a medication;

a carrier reservoir for storing a carrier, wherein the carrier reservoir is larger than the medication reservoir;

a mixing chamber in which the medication and carrier are thoroughly mixed, thus diluting the medication with the carrier, said mixing chamber being a micro fluidic chip having a capillary pathway disposed in a serpentine pattern;

a medication flow path fluidly connecting the medication reservoir to the mixing chamber;

a carrier flow path fluidly connecting the carrier reservoir to the mixing chamber;

a medication pump system for discharging the medication to the mixing chamber;

a carrier pump system for discharging the carrier to the mixing chamber;

an outlet port fluidly connected to the mixing chamber for discharging a diluted medication/carrier mixture; and

a bolus port disposed between the mixing chamber and the outlet port.

2. (Canceled)

3. (Original) The implantable infusion apparatus of claim 1, further comprising:

a medication flow restrictor disposed in the medication flow path to restrict a flow of the medication between the medication reservoir and the mixing chamber.

4. (Original) The implantable infusion apparatus of claim 1, further comprising:

a carrier flow restrictor disposed in the carrier flow path to restrict a flow of the carrier between the carrier reservoir and the mixing chamber.

5. (Original) The implantable infusion apparatus of claim 4, further comprising:

a medication flow restrictor disposed in the medication flow path to restrict a flow of the medication between the medication reservoir and the mixing chamber.

6. (Original) The implantable infusion apparatus of claim 5, wherein the medication flow restrictor is more restrictive than the carrier flow restrictor.

7. (Original) The implantable infusion apparatus of claim 5, wherein the medication flow restrictor is less restrictive than the carrier flow restrictor.

8. (Original) The implantable infusion apparatus of claim 1, wherein the medication flow path is more restrictive than the carrier flow path.

9. (Original) The implantable infusion apparatus of claim 1, wherein the medication flow path is less restrictive than the carrier flow path.

10. (Original) The implantable infusion apparatus of claim 1, wherein the medication pump system has a medication discharge rate and the carrier pump system

has a carrier discharge rate, and the medication discharge rate is greater than the carrier discharge rate.

11. (Original) The implantable infusion apparatus of claim 1, wherein the medication pump system has a medication discharge rate, and the carrier pump system has a carrier discharge rate and the medication discharge rate is less than the carrier discharge rate.

12. (Original) The implantable infusion apparatus of claim 1, wherein the medication pump system and the carrier pump system comprises a power cell selected from the group consisting of a two-phase fluid power cell associated with the medication and the carrier reservoirs, the fluid in the power cell vaporizing at physiological temperatures and a gas pressurized power cell charged with a propellant.

13. (Original) The implantable infusion apparatus of claim 1, wherein the medication pump system and the carrier pump system comprises a battery operated system.

14. (Canceled)

15. (Original) The implantable infusion apparatus of claim 3, wherein the medication flow restrictor is a micro fluidic chip.

16. (Original) The implantable infusion apparatus of claim 4, wherein the carrier flow restrictor is a microfluidic chip.

17. (Original) The implantable infusion apparatus of claim 1, further comprising a housing enclosing the implantable infusion apparatus wherein the housing is sized to be implantable in the human body.

18. (Original) The implantable infusion apparatus of claim 1, further comprising:

a medication access port to access the medication reservoir and covered with a medication compound septum; and

a carrier access port to access the carrier reservoir and covered with a carrier compound septum.

19. (Previously Presented) An implantable infusion apparatus comprising:
a medication reservoir for storing a medication;

a carrier reservoir for storing a carrier, wherein the carrier reservoir is larger than the medication reservoir;

a mixing chamber in which the medication may be mixed with and diluted by the carrier, said mixing chamber being a microfluidic chip having a capillary pathway disposed in a serpentine pattern;

a medication flow path fluidly connecting the medication reservoir to the mixing chamber;

a carrier flow path fluidly connecting the carrier reservoir to the mixing chamber;

a medication pump system for discharging the medication into the mixing chamber;

a carrier pump system for discharging the carrier into the mixing chamber;

an electronically controlled medication flow selector disposed in the medication flow path for controlling a discharge rate of the medication to the mixing chamber;

an outlet port fluidly connected to mixing chamber for discharging a diluted medication/carrier mixture; and

a bolus port disposed between the mixing chamber and the outlet port.

20. (Original) The implantable infusion apparatus of claim 19, wherein the medication flow selector is one of a valve and a pump.

21. (Original) The implantable infusion apparatus of claim 19, wherein the medication flow selector further comprises a controller for altering the medication discharge rate.

22. (Original) The implantable infusion apparatus of claim 19, further comprising:

an electronically controlled carrier flow selector disposed in the carrier flow path for controlling a discharge rate of the carrier to the mixing chamber.

23. (Original) The implantable infusion apparatus of claim 22, wherein the carrier flow selector is one of a valve and a pump.

24. (Previously Presented) The implantable infusion apparatus of claim 22, wherein the carrier flow selector further comprises a controller for altering the carrier discharge rate.

25. (Canceled)

26. (Previously Presented) The implantable infusion apparatus of claim 19, further comprising:

a medication flow restrictor disposed in the medication flow path prior to the medication flow selector for restricting the flow of the medication between the medication reservoir and the mixing chamber.

27. (Previously Presented) The implantable infusion apparatus of claim 19, further comprising:

a carrier flow restrictor disposed in the carrier flow path to restrict the flow of the carrier between the carrier reservoir and the mixing chamber.

28. (Previously Presented) The implantable infusion apparatus of claim 26, further
comprising:

a medication flow restrictor disposed in the medication flow path prior to the medication flow selector to restrict the flow of the medication between the medication reservoir and the medication flow selector.

29. (Previously Presented) The implantable infusion apparatus of claim 27, wherein the medication flow restrictor is more restrictive than the carrier flow restrictor.

30. (Previously Presented) The implantable infusion apparatus of claim 27, wherein the medication flow restrictor is less restrictive than the carrier flow restrictor.

31. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the medication flow path is more restrictive than the carrier flow path.

32. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the medication flow path is less restrictive than the carrier flow path.

33. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the carrier pump system has a carrier discharge rate and the medication discharge rate is greater than the carrier discharge rate.

34. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the carrier pump system has a carrier discharge rate and the medication discharge rate is less than the carrier discharge rate.

35. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the medication pump system and the carrier pump system comprises a power cell selected from the group consisting of a two-phase fluid power cell associated with the medication and the carrier reservoirs, the fluid in the power cell vaporizing at physiological temperatures and a gas pressurized power cell charged with a propellant.

36. (Previously Presented) The implantable infusion apparatus of claim 19, wherein the medication pump system and the carrier pump system comprises a battery operated system.

37. (Canceled).

38. (Previously Presented) The implantable infusion apparatus of claim 26, wherein the medication flow restrictor is a micro fluidic chip.

39. (Previously Presented) The implantable infusion apparatus of claim 27, wherein the carrier flow restrictor is a microfluidic chip.

40. (Previously Presented) The implantable infusion apparatus of claim 19, further comprising a housing enclosing the implantable infusion apparatus wherein the housing is sized to be implantable in the human body.

41. (Previously Presented) The implantable infusion apparatus of claim 19, further comprising:

a medication access port to access the medication reservoir and covered with a medication compound septum; and

a carrier access port to access the carrier reservoir and covered with a carrier compound septum.

42. (Previously Presented) A method of infusing medication comprising:

storing a medication in a medication reservoir;

storing a carrier in a carrier reservoir, wherein the carrier reservoir is larger than the medication reservoir;

discharging the medication to a mixing chamber;

discharging the carrier to the mixing chamber;

mixing the medication with the carrier in the mixing chamber to dilute medication and form a medication/carrier mixture, wherein the mixing chamber is a micro fluidic chip having a capillary pathway disposed in a serpentine pattern; ~~and~~

discharging the diluted medication/carrier mixture; and

introducing a bolus dosage into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture.

43. (Canceled)

44. (Previously Presented) The method of claim 42, further comprising: restricting the discharge of the medication.

45. (Previously Presented) The method of claim 42, further comprising: restricting the discharge of the carrier.

46. (Previously Presented) The method of claim 45, further comprising: restricting the discharge of the medication.

47. (Previously Presented) The method of claim 46, further comprising:

restricting the discharge of the medication more than the discharge of the carrier.

48. (Previously Presented) The method of claim 46, further comprising:

restricting the discharge of the carrier more than the discharge of the

medication.

49. (Previously Presented) The method of claim 42, wherein the mixing step comprises:

contacting the medication with the carrier in the mixing chamber;

flowing a contacted medication/carrier mixture through a series of mixing elements; and

delaying the discharging of the diluted medication/carrier mixture until the medication is diluted to the proper dosage.

50. (Previously Presented) A method of infusing medication comprising:

storing a medication in a medication reservoir;

storing a carrier in a carrier reservoir, wherein the carrier reservoir is larger than the medication reservoir;

controlling the discharge of the medication into a mixing chamber;

discharging the carrier into the mixing chamber;

mixing the medication with the carrier in the mixing chamber to dilute it to form a diluted medication/carrier mixture, wherein the mixing chamber is a micro fluidic chip having a capillary pathway disposed in a serpentine pattern;

discharging the diluted medication/carrier mixture; and

introducing a bolus dosage into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture.

51. (Canceled)

52. (Previously Presented) The method of claim 50, further comprising:

restricting the discharge of the medication.

53. (Previously Presented) The method of claim 50, further comprising:

restricting the discharge of the carrier.

54. (Previously Presented) The method of claim 50, further comprising:

restricting the discharge of the medication.

55. (Previously Presented) The method of claim 54, further comprising: restricting the discharge of the medication more than the discharge of the carrier.

56. (Previously Presented) The method of claim 54, further comprising:

restricting the discharge of the carrier more than the discharge of the medication.

57. (Previously Presented) The method of claim 50, wherein the mixing step comprises:

contacting the medication with the carrier in the mixing chamber;

flowing a contacted medication/carrier mixture through a series of mixing elements; and

delaying the discharging step until the medication is diluted to the proper dosage.

Evidence Appendix

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

Related Proceedings Appendix

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.